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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/518,867 | 02/15/2006 | Chad Munro | 8932-1036-999 | 5650 |
| 51832 | 7590 | 12/01/2006 | EXAMINER | |
| JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702 | | | YANG, ANDREW | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/518,867

Applicant(s)

MUNRO ET AL.

Examiner

Andrew Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Switzerland on 06/21/2002. It is noted, however, that applicant has not filed a certified copy of the Swiss application as required by 35 U.S.C. 119(b).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 16, 17, and Da. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

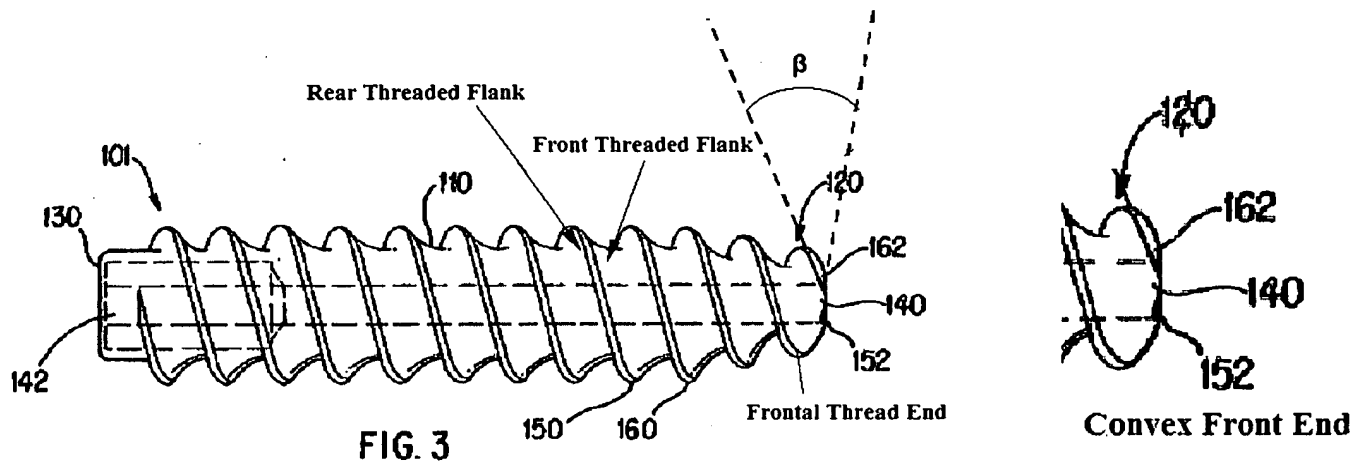
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 4, 9, 13, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Boucher (US Pat. No. 5443509).



Referring to the Figure 3, Boucher discloses a bone screw having a longitudinal axis and a threaded shaft comprising a cylindrical shank 110 and a threaded section, having an external diameter. The threaded section has a frontal thread end and a thread profile, wherein the thread profile has a front threaded flank directed towards the frontal end, a rear threaded flank, and a flank angle β . The threaded section has multiple threads and preferably a double threaded design consisting of threads 150 and 160. It is also disclosed that threads 150 and 160 can consist of sharp edges to cut threads as the screw advances (Column 3, Lines 40-43). Threads 150 and 160 terminate at the tip 120, resulting in a knife like element with a cutting edges 154 and 164 at the frontal thread end. The cutting edge goes around the shaft 110 helically and is curved convexly at the tip 120. Also, when viewed from the tip 120 (Figure 4) the cutting edges 164 and 154 extend radially from the shaft 110, but then continue in a sickle-shape with the cutting edges disposed on the outer edge. Furthermore, the front

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end or tip portion 120, which has a convex shape as seen in the enlarged view of tip 120, which, coincides with the frontal thread end.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-8, 10-12, and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Boucher.

Boucher discloses a bone screw having a longitudinal axis and a threaded shaft comprising cylindrical shank 110 and a threaded section, having an external diameter. The threaded section has a frontal thread end and a thread profile, wherein the thread profile has a front threaded flank directed towards the frontal end, a rear threaded flank, and a flank angle β . The threaded section has multiple threads and preferably a double threaded design consisting of threads 150 and 160. It is also disclosed that threads 150 and 160 can consist of sharp edges to cut threads as the screw advances (Column 3, Lines 40-43). Threads 150 and 160 terminate at the tip 120, resulting in a knife like element with a cutting edge at the frontal thread end. Furthermore, the front end or tip 120 of the device has a facet that results from the tip 120 being convex in shape. Boucher, however, fails to disclose the sector angle that the cutting edge encloses, the angle the knife-like element encloses, the cutting angle of the knife-like element, and the angle the facet makes with regards to the longitudinal axis. With regard to these

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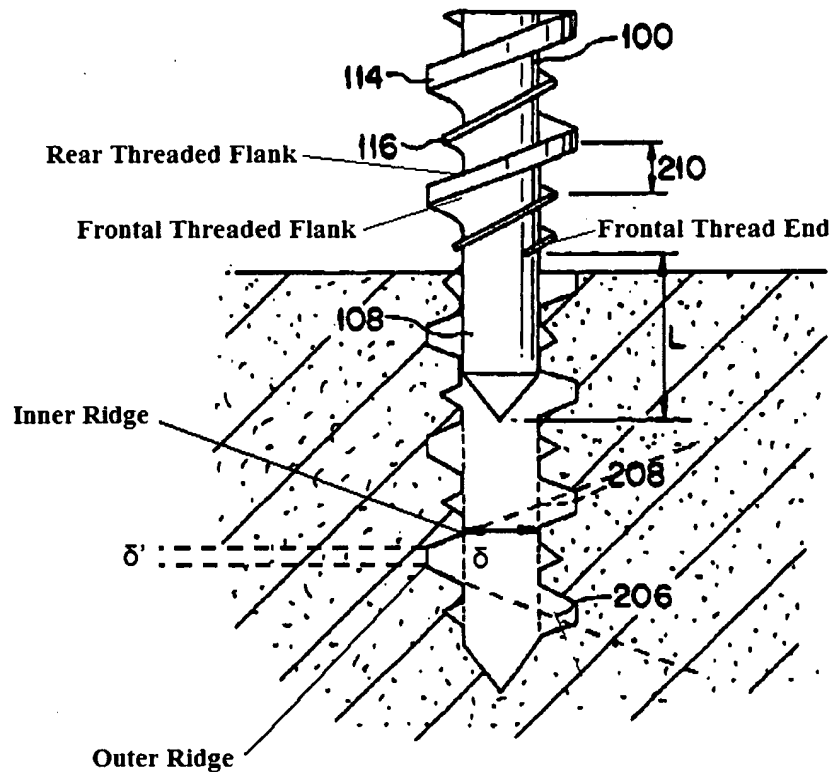
claims, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone screw of Boucher with the angles disclosed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin (US Pat. No. 6749233) in view of Boucher.

Baldwin discloses a medical screw having a longitudinal axis comprising a shaft 102 with a threaded portion 106 with an external diameter, a frontal thread end of threaded portion 106 as seen in Figure 3 on the next page, and a thread profile. The thread profile has a front threaded flank, a rear threaded flank, and a flank angle β . The threaded portion 106 is composed of multiple threads 114 and 116. Furthermore, Figure 3 shows the medical screw of Baldwin entering into a pre-tapped hole with threads to match, thus leaving a profile of the screw. The profile shows threads with an inner ridge with flank angle δ near the shaft 102 and an outer ridge with flank angle δ' wherein δ is greater than δ' . Baldwin fails to disclose a knife-like element with a cutting edge at the frontal thread end of the threaded section. Boucher, however, teaches a knife-like element with a cutting edge as previously stated to be able to cut threads as the screw advances as well as cut more aggressively into bone tissue (Column 5, Lines 54-59). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to construct the medical screw of Baldwin with a knife-like element

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with a cutting edge at the frontal thread end to improve the driving ability the screw into denser tissue such as bone.

**FIG. 3*****Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US. Pat. No. Re34969; 5743914; 5294227, 4655661; 5695497

Any inquiry concerning this communication from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached Monday-Friday 7:30 am – 5:00 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Eduardo Robert can be reached at 571-272-4719. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private Pair only. For More information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact Electronic Business Center (EBC) at 866-217-9197 (toll free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (USA OR CANADA) or 571-272-1000.

11/17/2006

AY



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER